IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant:	Gregory Grabowski, et al.	: Paper No:	
Serial No.	10/776,797	: Group Art Unit:	1651
Filed:	February 11, 2004	: Examiner:	Ganapathirama Raghu

For: LIPID HYDROLYSIS THERAPY FOR ATHEROSCLEROSIS AND RELATED DISEASES

RESPONSE TO RESTRICTION REQUIREMENT AND AMENDMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action, dated November 15, 2006, setting forth a restriction requirement in the above patent application, please consider the following remarks.

Also submitted concurrently is a petition for a one month extension to extend the time for response to January 15, 2005. A check in the required amount for the one month extension of time is enclosed.

In the Office Action, the Examiner has requested that the Applicant make an election between the following five groups of claims, which the Examiner contends represent five independent or distinct inventions. The Examiner has grouped the claims as follows:

I. Claims 37-50, drawn to a composition comprising a safe and effective amount of lipid hydrolyzing protein or polypeptide and a pharmaceutically acceptable carrier, classified in class 435, subclass 198;

II. Claims 51-61, drawn to a method of providing biologically active lipid hydrolyzing protein or polypeptide or mixtures thereof, to cells of a mammal having deficiency in biologically active lipid hydrolyzing protein or polypeptide, said method comprising administration into cells a vector comprising and expressing a DNA sequence encoding biologically active lipid hydrolyzing protein or polypeptide, classified in class 514, subclass 44;

III. Claims 62-63, drawn to a method of providing biologically active lysosomal acid lipase to cells of a mammal with atherosclerosis, comprising administration into cells a vector comprising and expressing a DNA sequence encoding lysosomal acid lipase, classified in 514, subclass 44;

IV. Claim 64, drawn to a method of treatment for Wolman's disease in a mammal comprising administering to said mammal a safe and effective amount of lysosomal acid lipase sufficient to treat the condition, classified in class 424, subclass 94.3;

V. Claim 65, drawn to a method of treatment for Cholesteryl Ester Storage disease in a mammal comprising administering to said mammal a safe and effective amount of lysosomal acid lipase sufficient to treat the condition, classified in class 424, subclass 94.3.

The Applicant respectfully traverses the restriction requirement for the following reasons.

The Examiner has not made a Prima Facie Showing that Combining the Claims of Group II and Group III would Impose a "Serious Burden" as Required by MPEP § 803.

The Examiner, in order to establish reasons for insisting upon restriction, must explain why there would be a serious burden on the Examiner if restriction is not required. MPEP §808.02. If the search and examination of all the claims in an application can be made *without* serious burden, the Examiner *must* examine them on the merits, even though they include claims to independent or distinct inventions. MPEP § 803. For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown by "appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02." To support a restriction requirement, the Examiner must provide reasons and/or examples to support conclusions to support the restriction requirement. MPEP § 803.

Applicant respectfully submits that the Examiner has not set forth a prima facie case that the restriction is proper, especially with respect to the restriction of claims 51-63 in groups II and III.

Specifically, the Applicant fails to see the basis for a "serious burden" on the Examiner in searching the claims of groups II and III. First, the claims of group II and II are not "separately classified;" as determined by the Examiner, all are within the same class and subclass. Second, there is no suggestion that the claims of group II and III have a "separate status" in the art. Applicant is unable to surmise from the detailed action why group II and group III, both directed towards DNA vector mediated administration of lipid hydrolyzing proteins, such as lysosomal acid lipase, would have such a "separate status in the art" such that restriction is appropriate, nor has the Examiner provided any evidence to support such a conclusion. Finally, there is no evidence to suggest that the claims of groups II and III are in a "different field of search." As groups II and III require a search of the *identical* class and subclass, and contemplate the same method (administration of a DNA vector) using related nucleotide sequences (that of lipid hydrolyzing proteins), it is unclear on what basis claims 51-63 would require a "different field of search."

Thus, in view of the above, Applicant respectfully submits that a prima facie case for restriction of the claims has not been made.

Combining Groups II and III would not impose a "Serious Burden" on the Examiner as Required by MPEP § 803.

In the event that the Examiner maintains that the prima facie case has been made as required by MPEP § 803, Applicant respectfully submits that the nature and scope of the claims of groups II and III would not impose a serious burden on the Examiner.

The Examiner would not be placed under a serious burden by combining groups II and III because both groups would necessarily be searched by the Examiner at the same time in class 514 subclass 44. That is, if a complete search is performed for group II, drawn to a method of providing biologically active lipid hydrolyzing protein or polypeptide using a DNA vector, group III will also be searched, as both groups are in the same class and subclass and all of these claims relate to a method of providing a biologically active lipid hydrolyzing protein or polypeptide to cells of a mammal comprising administering into cells a vector comprising a DNA sequence encoding the biologically active protein. The search for the invention defined by group III would be wholly encompassed by the search for the

invention defined by group II, as the group III claims encompass the same method using a type of lipid hydrolyzing protein claimed in group II.

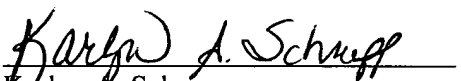
MPEP §803 states that even if a patent application contains independent and distinct inventions, "if the search and examination of all the claims in an application can be made without serious burden, the examiner *must* examine them on the merits." Therefore, even if one were to assume, for the sake of argument, that the claims of groups II and III do in fact define two separate inventions, the Examiner may consider all of them without serious burden because the claims all relate to methods of administering lipid hydrolyzing proteins or polypeptides via a DNA vector comprising a DNA sequence encoding biologically active lipid hydrolyzing protein, *which includes* the more specific type of lipid hydrolyzing protein, lysosomal acid lipase, as claimed in group III. Therefore, Applicant respectfully submits that the claims of groups II and III of the present application should be considered together.

In view of the above, withdrawal of this restriction requirement is requested and issuance of an office action covering claims 51-63 (groups II and III) of the instant application is earnestly requested.

In the event that the Examiner does not withdraw the restriction requirement and prosecute claims 51-63 together, then the Applicant provisionally elects the claims of Group II, claims 51-61 with traverse, for prosecution on the merits in the present application.

Respectfully submitted,

GREGORY GRABOWSKI

By 

Karlyn A. Schnapp
Registration No. 45,558
Attorney for Applicants
FROST BROWN TODD LLC
2200 PNC Center
201 East Fifth Street
Cincinnati, Ohio 45202
(513) 651-6865

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, this 16th day of January, 2007.

Linda Spore

Linda Spore

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